JAN 3 0 2006

K052654

1. IDENTIFICATION

- *Denomination:* **KLOCKNER dental implants**

- *Manufacturer name and address:* **SOADCO, S.L.**
Avgda. Fiter i Rossell, 4bis - Local n°2
ESCALDES - ENGORDANY
(ANDORRA)

- *Contact person:* **Maria Mitjaneta**

- *Telephone and Fax numbers:* **(376) 800 590** / Fax- **(376) 800 594**

- *Date:* **09/12/05**

2. DEVICE NAME

TRADE NAME: KLOCKNER implant System
Models: S3M

COMMON NAME: Dental Implant

CLASSIFICATION NAME: Root-form Endosseous Dental Implant (per 21CFR Part 872.3640)

3. PREDICATE DEVICE / LEGALLY MARKETED DEVICE

NAME: Dental endosseous implants

LEGALLY MARKETED DEVICE:
S3 KLOCKNER DENTAL IMPLANTS
NARROW NECK ITI STRAUMANN

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4.DESCRIPTION

The S3M Klockner implant are an endosseous implant, are a device made of Grade 3 commercially pure titanium , which consist of a small conical fixture (the root-form configuration), perhaps eigth to fourteen millimetres in length that have a shot peening process and a pasivated surface. Are available in diameter 3.1mm.

5.INTENDED USE OF THE DEVICE

S3M Klockner implants are a dental implant which consist of a small conical fixture (the root-form configuration)placed into a tiny receptacle channel which has been drilled into the bone under the gingiva (gum) at the desired location.

The gingiva is elevated from the underlying bone, the channel is cut, the fixture is placed, and the gingiva is sutured.

In its simplist form, the implant is used to substituiting the roots of teeth, to secure a denture. This is a wonderful remedy for an edentulous patient whose ridges do not allow the secure placement of a denture. In other uses the implant becomes the support for two or more (sometime many) implants for to support a bridge or multiple bridge. This implant is indicated for reduced spaces when this is insufficient for a conventional attachment (Ø 4,2 mm) or in areas which is very important the aesthetic and the conservation of the papila, in special in cases of single lateral incisors in the upper jaw and lateral and central incisors in the lower jaw.

6.BASIS FOR SUBSTANTIAL EQUIVALENCE

The subject Klockner implant are substantially equivalent to the previously cleared KLOCKNER DENTAL IMPLANTS(S3), NARROW NECK STRAUMANN implants. The intended use is identical to the predicate device. S3M Klockner implants are surgically placed in the maxillary or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients, in special for sites with poor space between teeth.

The implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropiate occlusal loading, in order to restore chewing function. In the case of edentulous patients many implants must be used.

The Klockner implants have the same material composition and the same surface treatment as previously cleared predicate dental implants, this surface treatment does not introduce new issues for biocompatibility. Mechanical testing was done in accordance with the FDA guidance «Information for premarket notification submissions for screw type endosseous implants» issued on December 9, 1996. Results from an independent laboratory showed that the surface treatment to have sufficient osseointegration. Additional test reports include finite elements analysis.

The proposed S3M klockner implants and accesories are identical to the curently marketed Klockner dental implants and accesories and similar in design, materials, and intended use to S3 Klockner dental implant and other legally marketed dental implant systems that are indicated for reduced space and to support other implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2006

Ms. Maria Mitjaneta
Quality Assurance Manager
SOADCO, S.L.
Avgda Fiter I Rossell, 4Bis Local n°2
ESCALDES- ENGORDANY
(ANDORRA)

Re: K052654
Trade/Device Name: KLOCKER DENTAL IMPLANT S3M
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 16, 2006
Received: January 23, 2006

Dear Ms. Mitjaneta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

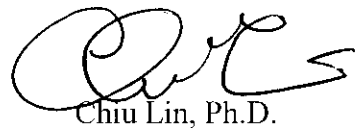
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052654

510(k) Number (if known): K010132

Device Name: KLOCKNER DENTAL IMPLANT S3M

Indications For Use:

S3M Klockner implants are a dental implant which consist of a small conical fixture (the root-form configuration). This implant enabling to be used as a support fitting when the gap to be replaced is not sufficient for a standard fitting (Ø 4.2 mm shoulder), or in areas of aesthetic concern, where the long-term preservation of the papilla is very important, such as the upper lateral incisors and lower incisors.

Susan Runyer

[illegible], General Hospital,
[illegible] Dental Devices

K052654

Prescription Use X **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)